UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,799	11/21/2005	Yoshikazu Yoshida	0234-0487PUS1	8682
2292 7590 09/22/2008 BIRCH STEWART KOLASCH & BIRCH			EXAMINER	
PO BOX 747	CH VA 22040 0747	KINGAN, TIMOTHY G		
FALLS CHURCH, VA 22040-0747		ART UNIT	PAPER NUMBER	
			1797	
			NOTIFICATION DATE	DELIVERY MODE
			09/22/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

	Application No.	Applicant(s)				
Office Action Comments	10/534,799	YOSHIDA, YOSHIKAZU				
Office Action Summary	Examiner	Art Unit				
	TIMOTHY G. KINGAN	1797				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠ Responsive to communication(s) filed on <u>10 Ju</u>	lv 2008 and 21 August 2008.					
<i>i</i> —	, _					
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
closed in accordance with the practice under Lx parte Quayre, 1900 O.D. 11, 400 O.G. 210.						
Disposition of Claims						
4)⊠ Claim(s) <u>2,5,6 and 8</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>2,5,6 and 8</u> is/are rejected.						
7) Claim(s) 2 is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement					
o) Claim(o) and dubject to restriction and on	olocion requirement.					
Application Papers						
9)☐ The specification is objected to by the Examiner.						
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received.						
	2. Certified copies of the priority documents have been received in Application No					
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)						
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. S) Notice of Informal Patent Application						
B) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5) Information Disclosure Statement(s) (PTO/SB/08) Other:						
1 apei 140(3)/iviali Date						

Application/Control Number: 10/534,799 Page 2

Art Unit: 1797

DETAILED ACTION

1. Claim 1 is withdrawn and Claims 3, 4, and 7 are cancelled. Claim 8 is new.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/10/2008 has been entered.

Response to Arguments

- 1. Examiner withdraws rejection on grounds of Yoshida, U.S. Patent Application Publication 2003/0232450. This reference represents applicant's own work and, as such, is not available as a 102(e) reference (MPEP 2139) in a rejection.
- 2. Applicant's arguments with respect to claims 2, 5-6 and 8 have been considered but are most in view of the new ground(s) of rejection.

Application/Control Number: 10/534,799 Page 3

Art Unit: 1797

Claim Objections

3. Claim 2 is objected to because of the following informalities: Parts (d) and (e) both comprise laminating "the third resin layer"; it appears part (e) should be "the fourth resin layer". Appropriate correction is required.

Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 6. Claims 2 and 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over M.R. McNeely et al., U.S. Patent Application Publication 2004/0109793 (herein after McNeely) in view of D. Chazan, U.S. Patent 6,752,966 (herein after Chazan).

For Claim 2, McNeely teaches the steps of fabricating a three-dimensional microfluidic device with a plurality of layers sealed together (abstract) and which may be

mounted on a reusable substrate [0076]. McNeely further teaches that multilayered microfluidic structures may be formed by laminating layers together, such layers comprising plastic tape [0017] or resins such as PTFE (resin films) and from which structures (grooves, inlets and outlets) may be cut by laser ablation techniques [0073]. McNeely does not teach the width of grooves.

Chazan teaches microfluidic devices the channels of which may be produced by laser ablation (col 1, lines 59-60), the width of which may be between 0.1 micron and about 1 millimeter (col 3, lines 62-65), within the range of the instant claim. McNeely teaches that the thickness of layers may be 10 microns to about 1 millimeter [0072] and that cutting of features may be controlled with use of an excimer laser to depths less than the entire thickness of the layer ([0064, [0073]), and that channels function in flow of fluids [0022]. McNeely and Chazan do not teach ablating a groove or throughhole in successive lamination as they are layered;

Chazan does teach that an ablatable polymer layer may be used as underlying substrate, provided such layer is non-ablatable under conditions used for ablation of the upper layer (col 8, lines 48-51). It would have been obvious to one of ordinary skill in the art, from the teachings of McNeely and Chazan on fabrication of multi-layered microfluidic devices and the control in depth of ablation to less than the depth of the ablatable polymer layer, to use, and with reasonable expectation of success, ablation of layers as they are successively laminated to the device during fabrication, such method of assembly being one of a limited number alternatives to the use of laser ablation in formation of grooved or stenciled polymeric layers with subsequent alignment and

lamination. Further, one of ordinary skill in the art would find desirable such steps comprising ablation as successive layers are added to the structure in order to provide for visually assisted alignment of features to be ablated with features previously ablated in underlying layers.

McNeely teaches multi-layered devices that permit disassembly for separation of reusable and disposable portions of the device ([0021], [0025]) (regenerate the microfluidic device).

McNeely teaches multi-layered (three dimensional) microfluidic devices that incorporate mixing technology [0031].

For Claim 5, McNeely teaches that layer thickness (resin film layer) may be 10 microns to about 1 millimeter [0072].

For Claim 6, McNeely does not teach the depths of each groove to be 20-30 microns. McNeely does teach that layer thickness may be 10 microns to about 1 millimeter [0072] and that cutting of features may be controlled with use of an excimer laser to depths less than the entire thickness of the layer ([0064, [0073]). Such teaching produces a range that, in depth of groove, brackets that of the instant claim. Further, the teaching would suggest to one of ordinary skill in the art that such ranges of the instant claim are within the capabilities for optimization found in the methods of McNeely.

7. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over McNeely and Chazan as applied to claim 2 above, and further in view of S.D. O'Connor et al., U.S. Patent 6,739,576 (herein after O'Connor).

Art Unit: 1797

For Claim 8, McNeely and Chazan do not teach the numbers of layers in the multi-layered device or the steps of repeating the lamination and ablation of the two additional resin layers. O'Connor teaches multi-layered microfluidic devices in which channels and chambers may be formed by laser ablation in one or more surfaces of a material or penetrate through a material (col 5, lines 50-52); O'Connor further teaches that such devices may have six layers (col 2, lines 52-53), their resins comprising adhesive tape of various materials, including polytetrafluoroethylenes (PTFE), and the layers adhered to on another by the steps of curing with pressure, temperature, chemical or optical interaction (col 5, lines 25-30) (the steps of laminating layers). It would have been obvious to one of ordinary skill in the art that a method of fabrication of a six-layered microfluidic device in the teaching of O'Connor, within the method of McNeely and Chazan comprising ablation after layers are assembled according to Claim 1, above, would comprise repetition of lamination and ablation of layers (for layers 4 and 5) prior to lamination of the top-most layer.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. S.J. Fonash et al., U.S. Patent Application Publication 2003/0157783.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY G. KINGAN whose telephone number is

Application/Control Number: 10/534,799 Page 7

Art Unit: 1797

(571)270-3720. The examiner can normally be reached on Monday-Friday, 8:30 A.M. to 5:00 P.M., E.S.T..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TGK /Jill Warden/

Supervisory Patent Examiner, Art Unit 1797